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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,886	02/27/2004	Andreas Reinmann	34088/US	4573

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EXAMINER

MCCORKLE, MELISSA A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/788,886

Applicant(s)

REINMANN, ANDREAS

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12192005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to amendment after non-final rejection received on 12/19/2005.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, 7, 17, 18, 19, & 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bokros (3,783,868). Regarding claims 1-3, Bokros teaches a implant having a surface with a surface structure improving ingrowth characteristics associated with the implant (column 12 lines 20-40) by promoting growth of cellular tissue in at least one direction relative to the surface of the implant (it has been shown that pyrolytic carbon coating [as used by Bokros] promotes cellular tissue growth-support for this found in additional reference, see attached), the implant comprising a non-biosorbable material (column 1 lines 10-26), and the surface structure is provided in a region of the implant, wherein after the implant is implanted the surface structure is generally adjacent to the skin (column 10 lines 60-65).

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3. Regarding claims 6 and 7, Bokros teaches the surface structure generally encircling the implant (column 5 lines 61-65), and the surface structure comprising one or more grooves (column 3 lines 29-30 and column 2 lines 59-62).
4. Regarding claims 17 and 18, Bokros teaches at least two regions on surface of implant provided with a surface structure (column 12 lines 20-40) and the implant further comprising a holding structure with at least one passage (fig 1 & 2A, and column 12 lines 20-40).
5. In regards to claim 19, Bokros teaches the implant as a port body (fig 1).
6. Regarding claims 20-26, Bokros teaches a surface structure on a surface of implant wherein the surface structure improves ingrowth characteristics associated with the implant (column 12 lines 20-40) wherein the surface structure promotes growth of cellular tissue in at least one direction relative to the surface of the implant (many studies show that the coating used by Bokros improves cellular growth-see attached reference for support) and the surface structure provided by turning a groove (column 2 line 58 – column 3 line 51). It is inherent to include the step of providing these structures for the method because the steps only include providing the claimed apparatus.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4, 5, and 8 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bokros. Bokros discloses applicant's basic inventive concept of an implant with surface structure, substantially as claimed with the exception of the specified dimensions. It would have been obvious to one of ordinary skill in the art to modify the widths and depths as claimed as a mere design choice lacking any criticality of size as being merely preferable for the intended target area (as Bokros teaches in column 4 line 55 – column 5 line 7) depending on the size of the area of the patient, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from Bokros above. The parameters in claims 4, 5, and 8-16 are deemed matters of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimal results.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bokros in view of Ragheb et al (US 6,096,070). Bokros discloses applicant's basic inventive concept of an implant with surface structure, substantially as claimed with the exception

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of the surface structure provided by etching. Ragheb et al. shows this feature to be old in the implant art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Ragheb et al. to modify the implant of Bokros by etching the surface structure for the purpose of altering the release rate of the materials or otherwise improve biocompatibility of surface of the layers.

Response to Arguments

11. Applicant's arguments filed 12/15/2005 have been fully considered but they are not persuasive. Applicant claims that the submitted amendment overcomes prior art of Bokros cited in first office action. However, the amendment added the functional language of "promoting growth of cellular tissue in at least one direction relative to the surface of the implant." It is pointed out that the implant of Bokros is coated with a pyrolytic carbon coating, which has been associated with enhanced endothelial cell growth in many studies (see attached article abstract, *Pyrolytic carbon coating enhances Teflon and Dacron fabric compatibility with endothelial cell growth*; although this article shows enhanced growth with Teflon and Dacron fabrics, it still shows that pyrolytic carbon coating enhances growth of cellular tissue.) Therefore, the amendments do not overcome the cited art, because the implant is capable of promoting cellular tissue growth.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



NICKOLAS D. LUCCHESI
PATENT EXAMINER
TECHNOLOGY CENTER 3700

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle
Examiner
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